UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA

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THE UNITED STATES OF AMERICA, and

THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, and WASHINGTON; THE DISTRICT OF COLUMBIA; THE COUNTY OF ALLEGHENY; and THE CITIES OF CHICAGO, NEW YORK, and PHILADELPHIA,

***ex rel.* JOHN DOE**

c/o Loretta Lynch, Esquire
Attorney General of the United States
U.S. Department of Justice
10th & Constitution Avenue, N.W.
Washington, D.C. 20530

Plaintiffs,

vs.

ATRICURE, INC., ST. HELENA HOSPITAL, AND ADVENTIST HEALTH

Defendants.

Civil No. [3:17-cv-10]

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

COMPLAINT

FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. § 3729 *et seq.*]; CALIFORNIA FALSE CLAIMS ACT [Cal. Govt. Code § 12650 *et seq.*]; COLORADO MEDICAID FALSE CLAIMS ACT [Colo. Rev. Stat. § 25.5-4-303 *et seq.*]; CONNECTICUT FALSE CLAIMS ACT FOR MEDICAL ASSISTANCE PROGRAMS [Conn. Gen. Stat. § 17b-301a *et seq.*]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. C. § 1201]; FLORIDA FALSE CLAIMS ACT [Fla. Stat. Ann. § 68.081 *et seq.*]; GEORGIA FALSE MEDICAID CLAIMS ACT [Ga. Code Ann. § 49-4-168 *et seq.*]; HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. § 661-21 *et seq.*]; ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT [740 Ill. Comp. Stat. § 175 *et seq.*]; IOWA FALSE CLAIMS ACT [Iowa Code § 685.1 *et seq.*; INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT [Ind. Code Ann. § 5-11-5.5-1 *et seq.*]; LOUISIANA MEDICAL ASSISTANCE PROGRAM INTEGRITY LAW [La. Rev. Stat. § 46:437.1 *et seq.*]; MARYLAND FALSE HEALTH CLAIMS ACT [MD Code Ann. § 2-601 *et seq.*]; MASSACHUSETTS FALSE CLAIMS LAW [Mass Gen

Laws ch.12 § 5 *et seq.*]; MICHIGAN MEDICAID FALSE CLAIMS ACT [Mich. Comp. Laws. § 400.601 *et seq.*]; MINNESOTA FALSE CLAIMS ACT [Minn. Stat. § 15C.01 *et seq.*]; MONTANA FALSE CLAIMS ACT [Mont. Code Ann. § 17-8-401 *et seq.*]; NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. § 357.010 *et seq.*]; NEW HAMPSHIRE FALSE CLAIMS ACT [N.H. REV. STAT. ANN. § 167:61-B *ET SEQ.*]; NEW JERSEY FALSE CLAIMS ACT, N.J. Stat. § 2A:32C-1, *et seq.*; NEW MEXICO MEDICAID FALSE CLAIMS ACT [N.M. Stat Ann. § 27-2F-1 *et seq.*]; NEW YORK FALSE CLAIMS ACT [N.Y. State Fin. § 187*et seq.*]; NORTH CAROLINA FALSE CLAIMS ACT [N.C.G.S. § 1-605 *et seq.*]; OKLAHOMA MEDICAID FALSE CLAIMS ACT [Okla. Stat. tit. 63 § 5053 *et seq.*]; RHODE ISLAND FALSE CLAIMS ACT [R.I. Gen. Laws. § 9-1.1-1 *et seq.*]; TENNESSEE FALSE CLAIMS ACT AND TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. § 4-18-101 *et seq.* and § 71-5-181 *et seq.*]; TEXAS MEDICAID FRAUD PREVENTION LAW [Tex. Hum. Res. Code Ann. § 36.001 *et seq.*]; VERMONT FALSE CLAIMS ACT [32 V.S.A. § 630 *et seq.*];VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Code Ann. § 8.01-216.1 *et seq.*]; WASHINGTON STATE MEDICAID FRAUD FALSE CLAIMS ACT [RCW § 74.66.005 *et seq.*];; DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. Code Ann. § 1-1188.13 *et seq.*]; ALLEGHENY COUNTY FALSE CLAIMS ACT [§ 485-1 *et seq.*]; CHICAGO FALSE CLAIMS ACT [Municipal Code §§ 1-

22-010, *et seq.*]; and NEW YORK CITY FALSE CLAIMS ACT [Local Law 53, Chapter 8 § 7-803]; PHILADELPHIA FALSE CLAIMS ACT [§ 19-3601 *et seq.*].

COMPLAINT

Plaintiff and *qui tam* Relator John Doe through his attorneys Sanford Heisler, LLP and Rabon Law Firm, PLLC, for his Complaint against the Defendants AtriCure, Inc., St. Helena Hospital, and Adventist Health (hereinafter "Defendants") alleges as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the Plaintiff States (collectively, the "Government") arising from false and/or fraudulent statements, records, and claims made and caused to be made by the Defendants and/or their agents and employees, which resulted in numerous false claims to both the Medicare and Medicaid programs in violation of the Federal False Claims Act, 31 U.S.C. §3729 *et seq.,* (hereinafter "the FCA") as well as the corresponding state false claims acts.

2. Since at least 2011, Defendants individually and/or in concert perpetrated a widespread, systematic and ongoing scheme to defraud the Government by knowingly causing Medicaid and Medicare to pay millions of dollars in false claims by: (1) promoting AtriCure products for use in certain procedures to treat atrial fibrillation that were not approved by the United States Food & Drug Administration; (2) violating the terms of a Corporate Integrity Agreement imposed on Defendants by the Office of Inspector General of the United States Department of Health and Human Services; (3) encouraging hospitals and physicians to engage in a fraudulent scheme to secure reimbursement for two procedures performed on the same patient that were medically unnecessary and/or manipulated in a way to ensure that the second procedure would become necessary; and (4) timing the two procedures at least 30 days apart for the sole purpose of maximizing reimbursement rather than for any medical purpose.

3. Defendants intentionally concealed their wrongful conduct from the Government, submitting and causing the submission of false claims to the Government and costing taxpayers millions of dollars annually.

II. PARTIES

4. Relator is a resident of Boulder, Colorado. Relator holds a Bachelor of Arts degree and a computer science degree. Relator worked for two medical device companies other than AtriCure between 2003 and 2010.

5. From 2011 until 2016, Relator was employed by Defendants as a Regional Sales Manager. As the Regional Sales manager, Relator was responsible for all sales and customer relationships for Defendant in the states within his territory. Relator also managed a team of clinical specialists and ablation specialists for case coverage and training labs.

6. Defendant AtriCure is a medical device company that specializes in creating equipment used to treat atrial fibrillation. Defendant AtriCure is headquartered at 7555 Innovation Way Mason, Ohio 45040 and operates all across the country, including in the Western District of North Carolina.

7. Defendant Adventist Health is a healthcare organization that operates about twenty hospitals in California, Hawaii, Oregon, and Washington. Adventist Health is headquartered at 2100 Douglas Boulevard, Roseville, CA 95661. Adventist Health operates St. Helena Hospital in Napa Valley.

8. St. Helena Hospital is a hospital located at 10 Woodland Road, St. Helena, CA 94574.

III. JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the allegations or transactions in this Complaint. Moreover, Relator is the original source of the information on which the allegations of this lawsuit are based.

10. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a), which provides for nationwide service of process. Further, Defendants have at least minimum contacts with the United States.

11. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), because Defendant AtriCure can be found in, reside in, and have transacted and continue to transact business in the Western District of North Carolina.

IV. APPLICABLE LAW

A. The Medicare Program

12. Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq*., established the federal Medicare health insurance program for the elderly and disabled. It is the nation's largest health insurance program and covers nearly 40 million people. Medicare is administered by the United States Department of Health and Human Services, through its agency, the Centers for Medicare and Medicaid Services ("CMS").

13. Medicare operates by authorizing payments in accordance with government-established conditions and rates for in-patient and out-patient healthcare services to "providers,"

such as hospitals, skilled nursing facilities, outpatient rehabilitation facilities, and home health agencies. 42 U.S.C. §§ 1395cc(a), 1395x(u).

14. Medicare Part A is hospital insurance that helps cover certain types of care provided by institutional providers within specified limits, included institutions providing home healthcare. *See* 42 U.S.C. § 1395c. Medicare Part B (Medical Insurance) covers some medical services that Part A does not cover, such as some of the services of physical and occupational therapists, and some healthcare. *Id.*

15. In order to participate in the Medicare program, a healthcare provider must enter into an agreement ("Provider Agreement") with the Secretary of HHS. 42 U.S.C. § 1395. After entering into a Provider Agreement, Medicare directly pays the provider a pre-determined rate for care provided to covered patients.

16. Under Medicare regulations, the term "provider" includes an institution providing home healthcare that has in effect an agreement to participate in Medicare. See 42 C.F.R. § 400.202. A provider must comply with the requirements of the program in order to be eligible to receive payments from the program for home health services.

17. Under the Medicare program, "no payment may be made under Part A or Part B for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of the malformed body member." 42 U.S.C. § 1395y(a)(1)(A). To satisfy this standard, providers must provide, among other things, economical medical services, along with evidence that the service will be of a quality that meets professionally recognized standards of healthcare and will be supported by evidence of medical necessity and quality. 42 U.S.C. § 1320c-5(a)(1-3).

18. In order to qualify for payments by Medicare for services provided, including home health services, providers must submit an enrollment application to the program on its Form CMS 855A. Among other things, the application requires providers to sign a certification that states in relevant part:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

19. The Medicare Claims Processing Manual specifies that a patient should be placed on a "leave of absence" when "readmission is expected and the patient does not require a hospital level of care during the interim period. Examples could include, but are not limited to, situations where surgery could not be scheduled immediately, a specific surgical team was not available, bilateral surgery was planned, or when further treatment is indicated following diagnostic tests but cannot begin immediately." Chapter 3. § 40.2.5. The Manual is clear that "[p]lacing a patient on a leave of absence will not generate two payments. Only one bill and one DRG payment is made." *Id.*

20. A Quality Improvement Organization may "review acute care hospital admissions occurring within 30 days of discharge from an acute care hospital if both hospitals are in the QIO's jurisdiction and if it appears that the two confinements could be related." *Id.*

B. The Medicaid Program

21. Medicaid is a federal and state funded health program, benefiting "categorically eligible" people, who are mostly low-income individuals and families. Like Medicare, it was created in 1965 pursuant to Title XIX of the Social Security Act. Under Medicaid, participating states administer state Medicaid programs that subsidize healthcare coverage for eligible residents. The individual state programs reimburse medical providers and hospitals for services rendered to program participants. The states receive federal funds to pay for Medicaid services.

22. Each state's Medicaid program must cover hospital services, 42 U.S.C. § 1396(a)(10)(A), 42 U.S.C. § 1396d(a)(12), and uses a cost reporting method similar to that used under Medicare.

23. Each physician who participates in the Medicaid program must sign a Medicaid provider agreement with his or her state. Although there are variations in the agreements among the states, all states require the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, including the fraud and abuse provisions.

24. Similar to Medicare coverage requirements, medical services must be reasonable and medically necessary in order to be subsidized by Medicaid. Claims for reimbursement presented by a provider to a state Medicaid program are subject to terms of certification. These terms require that the medical services for which the claims are sought were provided in accordance with applicable federal and state laws.

25. Medicaid programs also restrict providers from billing for multiple DRGs where a patient is readmitted in a short timeframe. For example, Michigan Department of Health and Human Service's Medicaid Provider Manual states that "[r]eadmissions within 15 days for a

related condition, whether to the same or a different hospital, are considered a part of a single episode for payment purposes." § 2.3.A.6.

C. Off-Label Marketing

26. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, states that companies may not market medical devices in the United States without prior approval from the Food and Drug Administration ("FDA") for the device's intended use. 21 U.S.C. § 360. In order to market Class III devices, like those at issue in the present case, manufacturers must submit a comprehensive application to the FDA for premarket approval. 21 U.S.C. § 360(e)(c).

27. Manufacturers can avoid the premarket approval process in two ways: the investigational device exception and the 510(k) clearance. The 510(k) clearance is based upon prior approval of a "substantially equivalent" device. 21 U.S.C. § 360; 21 C.F.R. § 807.87(k). The 510(k) clearance is not equivalent to FDA approval, and it limits cleared usage of the device to the intended indications listed in the application. 21 U.S.C. § 352(f); 21 C.F.R. § 801.5; 21 C.F.R. § 807.97. These indications must be listed on the label.

28. A manufacturer may only promote a device for cleared or approved indications. 21 U.S.C. § 352(f); 21 C.F.R. § 807.81(a)(3). Accordingly, promotion of a device for non-approved indications is considered "off-label" and is unlawful. 21 U.S.C. § 331(d); *see also United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 317 (D. Mass. 2011). Though off-label use of medical devices by doctors is not per se unlawful, medical device manufacturers may not market such off-label use. *See, e.g., Svidler v. U.S. Dep't of Health & Human Servs.*, No. C 03-3593, 2004 U.S. Dist. LEXIS 18325, *14, 2004 WL 2005781, at *5 (N.D. Cal. Sept. 8, 2004) ("[T]he FDA

can restrict a company from marketing off-label uses, but cannot prevent a doctor from prescribing a device for an off-label use for any purpose she deems medically necessary." (citing *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998))).

D. Corporate Integrity Agreements

29. Courts have further clarified that a company's failure to comply with its CIA obligations can result in False Claims Act liability. For instance, in *United States ex rel. Boise v. Cephalon*, the relators alleged that Cephalon failed to comply with CIA terms requiring it to notify OIG of any reportable events and certify that the company has an effective compliance program. No. 08-287, 2015 U.S. Dist. LEXIS 94448, at *4 (E.D. Pa. Jul. 21, 2015) (attached as Exhibit A). The CIA in that case also included stipulated penalties as a contractual remedy. *Id.* at *4—5. The Eastern District of Pennsylvania found that Cephalon's violations triggered False Claims Act liability because the "stipulated penalty provisions are construed as contractual obligations." *Id.* at 9—10 (quoting *United States v. Jupiter Aluminum Corp.*, No. 07-262, 2009 U.S. Dist. LEXIS 12388, at *7 (N.D. Ind. Feb. 18, 2009)). The court further found that this obligation becomes due as soon as the contract is breached. *Id.* at 17. Cephalon had therefore knowingly avoided an obligation to pay the government the Stipulated Penalties by failing to report its violations of healthcare laws.

30. In reaching this decision, the court followed *Ruscher v. Omnicare, Inc.* The Southern District of Texas in that action agreed with the relator's theory that Defendants "allegedly breached [the Corporate Integrity Agreement] by failing to notify the government of . . . probable violations of applicable laws." By falsely representing to the government that it *was* in compliance with the CIA, Omnicare avoided the Stipulated Penalties that it would have otherwise faced for

breaching the CIA. No. 4:08-CV3396, 2014 U.S. Dist. LEXIS 123831, at *12—13 (S.D. Tex. Sept. 5, 2014).[1] (attached as Exhibit B).

V. FACTUAL ALLEGATIONS

A. Background

a. *The Cox IV Maze Atrial Fibrillation Procedure*

31. The Cox-Maze procedure was first introduced by Dr. James Cox in 1987, and at the time it was the first surgical procedure to treat atrial fibrillation. This open-chest procedure utilized a "biatrial 'cut and sew' technique in an attempt to guide the native sinus impulse to both the atria and the atrioventricular (AV) node while blocking all possible macroreentrant circuits."[1] The procedure sought to reduce the risk of thromboembolism, stroke, and hemodynamic compromise by "restoring sinus rhythm and AV synchrony while maintaining atrial transport function."[2] A number of technical complications caused surgeons to further modify the original Cox-Maze procedure, ultimately resulting in the Cox-Maze III.[3] The Cox Maze III became the gold standard for surgical treatment of atrial fibrillation, but remained relatively unpopular due to its complexity.[4]

32. In 2002, surgeons began replacing the Cox Maze III's incisions with "a combination of bipolar radiofrequency and cryothermal ablation lines."[5] This procedure was

[1] Jason O. Robertson, Illustrated Techniques for performing the Cox Maze IV Procedure through a Right Mini Thoracotomy, Annals of Cardiothoracic Surgery (Jan. 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904342/.
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] *Id.*

termed the Cox Maze IV. The Cox Maze IV procedure uses radiofrequency energy or cryoablation to create "transmural lesions" analogous to the lesions created by the more traditional cut and sew technique pioneered by the original Cox Maze procedure.[6] The Cox Maze IV lesions are similar to those of the Cox Maze III, but the procedure may be performed more quickly than the Cox Maze III and allows for the possibility of minimally invasive procedures. The Cox Maze IV is a standard surgical procedure in the cardiology community that is reimbursed by Medicare and other government health insurance programs.

b. Minimally Invasive Procedures

33. Dr. Randy Wolf later pioneered a method that would allow surgeons to perform the Cox Maze lesions without opening the patient's chest. These minimally invasive, or "thoracoscopic", Cox Maze procedures go by several different names, including the TT Maze (Totally Thoracoscopic Maze), the VAT or VATs Maze (Video Assisted Thoracic Maze), the MIS Maze (Minimally Invasive Surgery Maze), the Mini Maze, and the Wolf Mini Maze. During these procedures, the surgeon threads a camera and surgical instruments through a small keyhole-sized incision between the ribs.[7] Guided by a fiberoptic camera, the surgeon then makes a series of lesions outside the heart using radiofrequency, energy, freezing, or ultrasonic energy.[8] These lesions are intended to destroy atrial tissue in areas known to conduct the electrical impulses that

[6] Open and Thoracoscopic Approaches to Treat Atrial Fibrillation and Atrial Flutter (Maze and Related Procedures, BlueCross BlueShield of Mississippi, http://www.bcbsms.com/com/bcbsms/apps/policysearch/views/viewpolicy.php?&noprint=yes&path=/policy/emed/maze_procedure.html (last visited Dec. 19, 2016).

[7] University of Southern California Keck School of Medicine, Maze Procedure for Treatment of Atrial Fibrillation, http://www.cts.usc.edu/mazeprocedure.html (last visited Dec. 19, 2016).

[8] Johns Hopkins Medicine, Heart & Vascular Institute, Minimally-Invasive Radiofrequency Ablation for Atrial Fibrillation, http://www.hopkinsmedicine.org/heart_vascular_institute/conditions_treatments/treatments/minimally_invasive_radiofrequency_ablation.html (last visited Dec. 19, 2016).

cause atrial fibrillation.[9] When performed successfully on appropriate patients, the minimally invasive approach to the Maze procedure "eliminates the need for dividing the breastbone (sternum), does not require the heart to be stopped, and does not require a heart-lung machine to be used. This often results in shorter recovery time and a lower risk of infection associated with open-heart surgery."[10]

c. *Hybrid Procedure*

34. From the moment Relator began working at AtriCure, the company had been endorsing a staged "Hybrid Maze" procedure for treating persistent atrial fibrillation.[11] The Hybrid Maze procedure combines a minimally invasive Cox Maze IV procedure performed by a cardiac surgeon with a subsequent catheter ablation by an electrophysiologist. After a cardiac surgeon performs a minimally invasive Cox Maze IV lesion set, an electrophysiologist performs a catheter ablation by guiding a tube into the patient's heart to destroy pieces of cardiac tissue that are causing the abnormal heartbeat.[12]

35. While it is the practice of some surgeons to perform the catheter ablation immediately after the minimally invasive surgical procedure, some electrophysiologists perform the catheter ablation on a separate day. According to Blue Cross Blue Shield of Mississippi, "[t]he rationale for doing a hybrid procedure is that a combination of both techniques may result in more complete ablation. Thoracoscopic epicardial ablation is limited by the inability to perform all possible ablation lines, because the posterior portions of the heart are not accessible via

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[9] *Id.*
[10] University of Southern California, *supra*.
[11] In October 2015, AtriCure purchased nContact, a company that marketed a similar procedure that was called the "nContact Convergent Procedure".
[12] Johns Hopkins Medicine, Health Library, Catheter Ablation, http://www.hopkinsmedicine.org/healthlibrary/test_procedures/cardiovascular/catheter_ablation_135,45/ (last visited Dec. 19, 2016).

thoracoscopy. Percutaneous, endoscopic ablation is limited by incomplete ablation lines that often require repeat procedures. By combining both procedures, a full set of ablation lines can be performed, and incomplete ablation lines can be minimized."[13]

B. The 30 Day Scheme

36. Defendants pushed surgeons to perform a permutation of the Hybrid Maze that would cause patients to develop atrial flutter and necessitate a second procedure that otherwise might not have been necessary. Additionally, Defendants encouraged surgeons to wait thirty days between the two procedures so that both the cardiac surgeon and the electrophysiologist could each bill for a procedure. This enabled the hospital to bill for two DRG's instead of one and to collect more money from Medicare and other government insurance programs than it was entitled to receive.

37. Joshua Cowan, Vice President of Strategy and Communication at Adventist Health in California, pioneered this scheme at St. Helena Hospital[14] in St. Helena, California and trained doctors on how to carry out the scheme at conferences paid for and organized by AtriCure. This scheme required hospitals to (1) ensure that patients would require the follow-up catheter ablation, and (2) schedule the catheter ablation more than 30 days after the cardiac surgeon performs the minimally invasive Cox Maze IV procedure.

38. Because some patients ultimately will not require the second stage of the hybrid procedure, the hybrid procedure is more profitable if surgeons can ensure that patients will return

[13] BCBS Mississippi, *supra.*

[14] St. Helena Hospital also conducts clinical trials for the AtriCure products for the FDA approval process. During the clinical trial procedures, doctors do not perform the unnecessary ablation.

for the catheter ablation. Relator uncovered a recording of a national sales meeting in Ohio in which AtriCure Director of Clinical Affairs Ken Frazier acknowledges that only 30-40% of patients require the second procedure. One way in which cardiac surgeons can ensure that patients will return for the catheter ablation is by performing an incomplete mitral isthmus ablation at the end of the minimally invasive Cox Maze IV procedure. The traditional Cox Maze IV procedure sometimes includes a complete ablation of the mitral isthmus. However, the mitral isthmus line is particularly difficult for the cardiac surgeon to complete thoracoscopically. This is one of the reasons why surgeons developed the hybrid procedure: the electrophysiologist is more capable of ablating lines such as the mitral isthmus and the tricuspid isthmus with a catheter ablation than the cardiac surgeon is with thoracoscopic Cox Maze IV.

39. Incomplete mitral isthmus ablations have been known to be "pro-arrhythmic".[15] As a result, in Relator's experience, most cardiac surgeons who take part in the Hybrid Maze procedure simply refrain from ablating the mitral isthmus altogether, or they leave this particular ablation entirely in the hands of the electrophysiologist.[16] By refraining from performing the mitral isthmus ablation, the cardiac surgeon acknowledges the limitations of the minimally invasive Cox Maze IV procedure and allows for the possibility that the catheter ablation will not be necessary. But if the cardiac surgeon instead performs an incomplete mitral isthmus ablation, then he all but ensures that the patient will develop atrial flutter and that the catheter ablation will be necessary not only to finish the Cox Maze IV lesion set, but also to repair the newly-created atrial flutter.

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[15] Kelvin CK Wong, A Review of Mitral Isthmus Ablation, Indian Pacing and Electrophysiology Journal (Jul.-Aug. 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3407408/.
[16] In AtriCure's DEEP AF study, the mitral isthmus line was omitted entirely.

40. Defendants trained cardiac surgeons to perform an incomplete mitral isthmus ablation during the minimally invasive Cox Maze IV, thus creating a high likelihood that the patient would develop atrial flutter and need a catheter ablation at a later date. The cardiac surgeon also used clips to mark the location where the flutter will occur so that the electrophysiologist can more easily find the gaps in his ablations. The incomplete mitral isthmus ablation then caused the patient to develop atrial flutter, necessitating a follow-up catheter ablation by the electrophysiologist. According to Relator, the patients were routinely informed that they would be returning for a second procedure. Upon information and belief, they were not informed that, in the absence of the incomplete mitral isthmus ablation, a second procedure may not have been necessary at all.

41. Additionally, the Hybrid Maze would be more profitable to Defendants if hospitals and physicians are able to bill for more than one procedure. Accordingly, once the cardiac surgeon has ensured that the patient will need to return for the catheter ablation, the hospital must schedule the catheter ablation more than 30 days after the cardiac surgeon's minimally invasive Cox Maze IV procedure, so that the hospital and the electrophysiologist may bill for the catheter ablation. The electrophysiologist's catheter ablation completes the Cox Maze IV lesion set and repairs the atrial flutter created by the incomplete mitral isthmus ablation performed by the cardiac surgeon. When the electrophysiologist performs his catheter ablations, he then bills for a full atrial fibrillation catheter ablation in order to ensure maximum reimbursement by Medicare and other government insurance programs. *See* Exhibit C at 2.

42. According to billing explanations of the Hybrid procedure commonly circulated by AtriCure employees, cardiac surgeons would report one of the following CPT codes for cardiac

tissue ablation: 33254 (Limited Maze), 33255 (Extensive maze without CPB), 33256 (Extensive maze with CPB), 33265 (Endoscopic limited), or 33266 (Endoscopic extensive).

43. Hospitals would report ICD-9 Procedure Code 37.37, which is then assigned to one of the following MS-DRGs: 228 (Other Cardiothoracic Procedure with MCC), 229 (Other Cardiothoracic Procedure with CC, or 230 (Other Cardiothoracic procedure without MCC/CC). Electrophysiologists would report up to four CPT codes for their role in the Hybrid procedures: 93651 (Catheter ablation), 93620 (Comprehensive EP evaluation), +93613 (3-D Mapping), and 93631 (Intra-operative pacing/mapping).

44. As a result of this scheme, and as explained by AtriCure documents, both the cardiac surgeon and the electrophysiologist receive maximum reimbursements for full ablation procedures on the same patient, and the hospital then receives reimbursement for two DRGs instead of just one.[17]

45. AtriCure and its partner hospitals trained physicians to act in this manner, because Medicare and other government insurance companies will not reimburse for more than one procedure to fix atrial fibrillation within a 30-day period. If the hospitals and physicians schedule the two procedures 30 or more days apart, the Hybrid procedure is significantly more profitable, because the hospitals and physicians will then bill for two procedures instead of one procedure performed jointly by two parties. The parties justify the second procedure with the existence of the newly-created flutter that they must now repair.

46. Relator is aware that Kevin Henderson, Director of Sales for the West Coast was intimately familiar with the 30-day scheme. Henderson discussed a training that took place at

[17] Upon information and belief, hospitals billed DRGs 250 (Percutaneous CV proc without stent with MCC) or 251 (Percutaneous CV proc without stent, without MCC (87%)) in addition to one of the previously mentioned DRGs. See Exhibit C at 4 (Hybrid_Maze_Cost_Analysis.pdf).

Rose Medical Center in Denver, Colorado in which Joshua Cowan, an executive of Defendant Adventist, gave a presentation that addressed the 30-day scheme.

47. Henderson noted that Cowan discussed the practice in the context of describing methods of securing more patient referrals for procedures using AtriCure products. Cowan had described a "staged procedure, at least 30 days out" that would enable two separate DRGs to be billed, in contrast to a procedure which would permit only one.

48. The foregoing illustrates that AtriCure knew that hospitals were encouraging physicians to insert a 30-day gap between the two stages of the Hybrid Maze procedure in order to unlawfully increase reimbursement. AtriCure representatives took part in the meetings where this unlawful billing procedure was discussed and AtriCure sales representatives actively encouraged this behavior. AtriCure further knew that there was little to no medical justification for the 30-day gap between stages. By training and encouraging physicians and hospitals to wait longer than necessary before completing the second stage of the procedure, AtriCure caused Medicare to pay physicians and hospitals more than the parties were entitled to. Accordingly, AtriCure caused the submission of false claims to the Government.

49. The foregoing is illustrative of a nationwide scheme by AtriCure to encourage hospitals and physicians to double-bill Medicare and other government insurance programs. The foregoing is not limited to the parties or hospitals mentioned above, but is merely an example illustrative of a broader nationwide scheme perpetrated by AtriCure and its partner hospitals to defraud Medicare and other government insurance programs.

C. Off-Label Marketing in Violation of AtriCure's Corporate Integrity Agreement

a. AtriCure's Corporate Integrity Agreement

50. In addition to the general prohibition against off-label marketing discussed earlier in the complaint, AtriCure's off-label marketing scheme also violates its January 27, 2010 Corporate Integrity Agreement (CIA), attached hereto as Exhibit D. AtriCure signed this agreement with the Department of Health and Human Services in connection with a Settlement Agreement that covered allegations that the company engaged in unethical conduct in the marketing of its products.

51. AtriCure's Corporate Integrity Agreement is the result of *United States ex rel. Doe v. AtriCure, Inc.*, 4:07-cv-02702, (S.D. Tex. 2009) (attached as Exhibit E). This case alleged that AtriCure engaged in an off-label marketing scheme to promote closed-chest surgical ablation procedures for which its products lacked indications. This scheme resulted in over 2000 "sole therapy, closed-chest, thoracoscopic ablation procedures." Exhibit E at paragraph 71. The case further alleged that AtriCure expanded off-label use of their products by "marketing their minimally invasive, standalone products by advising hospitals to take advantage of the Medicare system to obtain over-reimbursement for such procedures." Id. at paragraph 72. AtriCure accomplished this by "marketing the spread between the high DRG reimbursement for atrial fibrillation procedures using their products and the low cost of those procedures." This behavior is strikingly similar to that alleged by the instant complaint. Despite paying a $3.76 million-dollar settlement and entering into a corporate integrity agreement prohibiting off-label marketing, AtriCure continued to engage in a nearly identical scheme to market many of the same off-label procedures that they had just been punished for promoting.

52. Among other things, the CIA required the Company to adopt Policies and Procedures regarding "appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable FDA requirements, including FDA regulatory approval requirements", "appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute . . . and the False Claims Act", and "the materials and information that may be distributed by AtriCure, Inc. sales representatives and account executives about AtriCure, Inc.'s Government Reimbursed Products and the manner in which AtriCure, Inc.['s] sales representatives and account executives respond to requests for information about non-FDA approved (or "off-label") uses of AtriCure, Inc.'s Government Reimbursed Products."

53. The CIA also required the Company to train employees on "Federal healthcare program and FDA requirements relating to Promotional and Product Services Related Functions" and "examples of proper and improper practices related to Promotional and Product Services Related functions." AtriCure was also required to engage an Independent Review Organization that would monitor AtriCure's compliance with the Agreement.

54. The Agreement sets Stipulated Penalties, accumulating daily, for AtriCure's violations of the various terms of the Agreement. For example, the Agreement provides for a $2,500 Stipulated Penalty for each day that AtriCure fails to implement "the training of Covered Persons and Relevant Covered Persons" as described in the Agreement. There is also a $2,500 Stipulated Penalty for each day that AtriCure fails to report "Reportable Events." The CIA defines "Reportable Event" as "a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal healthcare program and/or

applicable to any FDA requirements relating to the promotion of AtriCure, Inc. Government Reimbursed Products for which penalties or exclusion may be authorized."

b. AtriCure's Off-Label Marketing Scheme

55. In spite of this agreement, AtriCure engaged in a marketing scheme to promote several of its products for off-label, closed-chest atrial fibrillation procedures. The following products are implicated by this scheme: The AtriCure Synergy Ablation System, EMR2 Synergy Clamp, EML2 Synergy Clamp, Max5 RF Pen, MLP1 RF Pen, MID1 Wolf Dissector, Fusion 150, AtriClip Pro, and Fusion 50. These products are only indicated for open-chest procedures like the traditional Cox Maze IV.

56. According to FDA 510k K093679, "the AtriClip LAA Exclusion System is indicated for the occlusion of the left atrial appendage, under direct visualization, in conjunction with other cardiac procedures." *See* Exhibit F. This device, also known as the AtriClip Pro, is used in all or almost all minimally invasive Cox Maze IV procedure in which a cardiac surgeon utilizes AtriCure products. *See* http://mmcts.oxfordjournals.org/content/2007/0723/mmcts.2007.002758.full (noting that "the left atrial appendage is always amputated or excluded" in a Cox Maze IV procedure). Other AtriCure devices used in the thoracoscopic atrial fibrillation surgery are indicated generally for cardiac ablation but not specifically for use in a thoracoscopic setting. The AtriCure Synergy OLL2/OSL2 clamps are approved to ablate cardiac tissue for the treatment of persistent AF or LSP AF in patients who are undergoing open concomitant CABG and/or valve replacement or repair. *See* Exhibit G. AtriCure Synergy Access and Synergy EMR2/EML2 clamps are cleared for cardiac tissue ablation. *See* Exhibit G.

57. The AtriCure Isolator multifunctional pen and Isolator linear pen are cleared to both diagnose cardiac arrhythmias and ablate cardiac tissue. See Exhibit H. The Isolator Transpolar Pen System is indicated for ablation of cardiac tissues during cardiac surgery using radiofrequency energy when connected to the AtriCure Ablation and Sensing Unit or for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device. *See* Exhibit H. ACC2 and cryoICE BOX devices, manufactured by AtriCure, are cleared for the treatment of cardiac arrhythmias when used with cryo1 and cryoICE.

58. The AtriCure Synergy Ablation System includes the Isolator Synergy clamp (long and standard), the AtriCure Switch Matrix, and the AtriCure ablation & sensing unit (ASU). Other devices used to complete Maze IV lesions, or which otherwise utilize "synergy technology" are the cryoICE cryo-ablation probe, the Isolator multifunctional pen (19cm), and the Isolator Synergy clamp (right curve and left curve). *See* Exhibit I. This system is indicated for "the ablation of cardiac tissue for the treatment of persistent atrial fibrillation (sustained beyond seven days, or lasting less than seven days but necessitating pharmacologic or electrical cardioversion) or longstanding persistent atrial fibrillation (continuous atrial fibrillation of greater than one-year duration) in patients who are undergoing open concomitant coronary artery bypass grafting and/or valve replacement or repair." *See* Exhibit J.

59. AtriCure began marketing these products for minimally invasive thoracoscopic Cox Maze IV procedures despite lacking indications for these procedures. These procedures include the standalone minimally invasive Maze procedure and the first stage of the Hybrid Maze procedure, among others. AtriCure marketed the minimally invasive procedures through a series of training sessions paid for by AtriCure.

60. None of these procedures were performed concomitantly with other procedures such as cardiac bypass or valve replacement or repair. AtriCure was advocating for the performance of these procedures, such as the hybrid maze or standalone minimally invasive maze, among others, strictly for the treatment of atrial fibrillation on a non-concomitant basis. In particular, AtriCure paid for and organized trainings at St. Helena Hospital, where Joshua Cowan, and others, trained physicians to perform a minimally invasive Cox Maze IV procedure (off-label), only partially ablate the mitral isthmus line, and then schedule the patient to return for a catheter ablation by an electrophysiologist.

61. AtriCure understood that electrophysiologists were in a position to recommend the procedure to many of their patients, and therefore wanted to include electrophysiologists in the procedure in order to obtain those referrals.

62. AtriCure set up training sessions at lavish resorts in vacation-oriented destinations and invited physicians with the clear intent of training them to perform off-label procedures. At these trainings, AtriCure-sponsored surgeons trained invitees on how to complete off-label atrial fibrillation procedures. For example, Exhibit K is an invitation to an AtriCure-sponsored training at the Westin New York Grand Central Hotel in November of 2015. While day one of the two-day event appeared to focus on the Cox Maze IV procedure in general, day two's agenda included presentations on "Integrating the Maze IV into non-sternotomy approaches," and an "Overview of minimally invasive tissue ablation."

63. The day two agenda also included a presentation on "Communication and Collaboration with Cardiology and EP colleagues." Exhibit K. These are clear references to the minimally invasive techniques for which AtriCure does not possess indications, including the hybrid approach detailed above. AtriCure-sponsored nearly identical "Maze IV Surgical Training

Course & Advanced Ablation Course[s]" at the Snowbird Resort in Snowbird, Utah in March of 2016 and at the Homewood Suites in Mason, Ohio in April 2016. Exhibits L and M.

64. Relator is aware that, at a national sales meeting in Ohio, AtriCure employees were instructed on how to circumvent the requirements of the CIA and continue to market off-label. Ken Frazier, Director of Clinical Affairs, acknowledged at the meeting that the DOJ enforcement action was a result of off-label marketing. Frazier then acknowledged that the company lacked the proper indications for minimally invasive atrial fibrillation treatment.

65. Frazier confirmed that AtriCure had devised the hybrid procedure with electrophysiologists to mitigate risk associated with marketing an off-label procedure after the company signed the CIA. Frazier went on to state that, while some were reluctant to discuss off-label procedures until they were FDA approved, most of his AtriCure colleagues had nevertheless already begun to discuss the procedure with providers. Frazier also noted that pushing patients to undergo the Hybrid Procedure was the most effective means through which to drive patients to secure billing for the Minimally Invasive Standalone procedure.

66. Additionally, Frazier gave a PowerPoint presentation on multiple occasions throughout the country on the strength and viability of a hybrid based approach to atrial fibrillation. The presentation markets an off-label thoracoscopic set of ablations by the cardiac surgeon, including the exclusion or excision of the left atrial appendage, and a subsequent endoscopic catheter ablation by an electrophysiologist. Exhibit N. Frazier gave this presentation, and other versions of it, throughout the country, at least as early as 2012.

67. Relator witnessed Frazier give this presentation in 2012 to Dr. John Mehall and Dr. Chris Cole at Penrose-St. Francis Medical Center in Colorado Springs, Colorado, to Dr. Thomas

Matthew and Dr. Rob Kiser at the Medical Center of the Rockies in Colorado, and to Dr. Chris Wehr and Dr. Brad Mikaelian at Memorial Hospital in Colorado Springs, Colorado.

68. In 2013, Relator witnessed Frazier give this presentation to Dr. Peter Forstall and Dr. Dave Affleck in Ogden, Utah and to Dr. David Silver and Dr. Eric Munoz in Cheyenne, WY. In 2014, Relator witnessed Frazier give this presentation to Dr. Rafe Connors and Dr. Michael Eifling at McKay Dee Hospital in Ogden, Utah and to Dr. Fred Han and Dr. Ganesh Kumpati in Salt Lake City, Utah.

69. In 2015, Relator witnessed Frazier give the presentation to Dr. John Doty, Dr. Dan Dan, Dr. Stephen Clason, Dr. Jared Bunch, and Dr. Mike Cutler at Intermountain Medical Center in Murray, Utah and to Dr. Sanjay Tripathy and Dr. Sri Sundaram in Denver, Colorado.

70. Slide 3 describes the procedure as both "[a] Combined endocardial-epicardial ablation procedure" and an "Afib and AFL combined procedure."[18] Exhibit N. This slide further explains that the end result of the Hybrid Procedure is the Cox Maze IV lesion set. *Id.* On the very next slide, the PowerPoint references the "Excision/exclusion [of the] LAA". *Id.* This is repeated on slide 18. *Id.* at 18. The AtriClip Pro is indicated for excision/exclusion of the LAA (left atrial appendage) but only under "direct visualization." Other AtriCure presentations indicate that the exclusion of the left atrial appendage is performed with the AtriClip. Exhibit O at 19. As stated above, the AtriClip Pro is only indicated for procedures done "under direct visualization." Exhibit F.

71. Notably, however, the entire presentation repeatedly references a thoracoscopic, minimally invasive approach to the epicardial portion of the Hybrid Procedure. As previously stated, the term "thoracoscopic" generally refers to a minimally invasive procedure assisted by a

[18] "AFL" stands for Atrial Flutter.

"thoracoscope," a thin, flexible video camera that surgeons insert through a small chest incision. Slide 6 states that "A Thoracoscopic epicardial approach makes surgical ablation less complex, easier and with better visualization." Exhibit N. Slide 11 is titled, "What is a minimally invasive technique, with an acceptable success rate and accepted EP endpoints?" *Id.* Slide 12, while discussing ideal techniques for persistent lone atrial fibrillation, mentions the "Percutaneous/Thoracoscopic" approach, with "percutaneous" referring to the electrophysiologist's catheter ablation and "thoracoscopic" referring to the cardiac surgeon's minimally invasive Cox Maze IV procedure. *Id.* at 12. Slide 13, while discussing the advantages of a thoracoscopic epicardial approach, specifically lists out the "LAA," or left atrial appendage. *Id.* at 13. Slide 25 states that "[a] thoracoscopic epicardial Endocardial approach makes surgical ablation much less complex and makes EP approach must (sic) faster." Exhibit N. This clearly indicates that the surgical approach envisioned during the hybrid procedure is, in fact, a minimally invasive, "thoracoscopic," procedure.

72. The above illustrates that AtriCure's clear motive in developing the Hybrid Procedure was to market and promote off-label, minimally invasive procedures for which its products did not have proper indications. This includes the thoracoscopic exclusion or excision of the left atrial appendage, a procedure completed by the AtriClip Pro despite the lack of direct visualization required by its indication. By marketing a two-part procedure that includes thoracoscopic Cox Maze IV lesion set, and notably, exclusion/excision of the left atrial appendage with the AtriClip Pro, AtriCure engaged in off-label marketing, thereby violating Medicare guidelines and the terms of its CIA.

73. Moreover, as recently as 2016, AtriCure paid its sales representatives commission based on the number of minimally invasive surgeries (MIS) the representatives arranged. This is

yet another indication of AtriCure's pervasive and ongoing intent to engaged in illegal off-label marketing. *See* Exhibit P at 1, 2 (stating that quarterly and annual bonuses will be based on results in categories including MIS or Minimally Invasive Standalone).

74. The foregoing allegations are illustrative of a broader, nationwide scheme to unlawfully market theatrial fibrillation products for off-label uses in violation of Medicare guidelines and AtriCure's CIA through a variety of channels and actors.

COUNT I
False Claims Act
31 U.S.C. §3729(a)(1)(A)

75. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

76. By virtue of the acts described above, Defendants knowingly submitted, caused to be submitted and continues to submit and to cause to be submitted false or fraudulent claims for payment and reimbursement by the United States Government by knowingly or recklessly making false and/or incomplete statements about the pricing of AtriCure, Inc. products as set forth above.

77. As set forth in the preceding paragraphs, Defendants violated 31 U.S.C. § 3729 and has thereby damaged and continues to damage the Government by its actions in an amount to be determined at trial.

COUNT II
False Claims Act
31 U.S.C. §3729(a)(1)(B)

78. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

79. Defendants have thereby damaged and continues to damage the United States Government by its actions in an amount to be determined at trial.

80. WHEREFORE, on Counts I and II, Relator on behalf of himself and the United States Government pray:

a. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of $10,781.40 and not more than $21,562.80 for each violation of 31 U.S.C. § 3729, and the costs of this action, with interest, including the costs to the United States Government for its expenses related to this action;

b. That the Relator be awarded all costs incurred, including reasonable attorneys' fees;

c. That, on those allegations for which the United States Government intervenes and continues to proceed with this action, the Relator be awarded an amount for bringing and prosecuting this action of at least 15% but not more than 25% of the proceeds of the action or settlement of the claim;

d. That, on those allegations for which the United States Government does not intervene or proceed with this action, the Relator be awarded an amount that the Court decides is reasonable for collecting the civil penalty and damages, which shall not be less than 25% or more than 30% of the proceeds of the action or settlement of the claim.

COUNT III
False Claims Act
31 U.S.C. § 3729 (a)(1)(C)

81. Relator realleges and reincorporates all the preceding paragraphs of the Complaint as if fully set forth herein.

82. By virtue of the acts described above, Defendants, together with others known and unknown, violated the False Claims Act by conspiring to knowingly and willfully cause the submission of false claims to obtain payments from Medicaid and Medicare.

83. It was a part of this conspiracy that Defendants and their co-conspirators knowingly and willfully submitted false claims to Medicaid and Medicare for ineligible medical services.

84. As a result of these false claims, the United States has been damaged and continues to be damaged in an amount to be determined at trial.

COUNT IV
California False Claims Act
Cal. Govt Code §12651(a)(1) and (2)

85. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

86. This is a claim for treble damages and penalties under the California False Claims Act.

87. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

88. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

89. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continue to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

90. By reason of Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

91. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

92. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of California in the operation of its Medicaid program.

COUNT V
Violation of the Colorado Medicaid False Claims Act
Colo. Rev. Stat. § 25.5-4-305

93. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

94. This is a claim for treble damages and penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-303., *et seq.*

95. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

96. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims.

97. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

98. By reason of Defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

99. The State of Colorado is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

100. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Colorado in the operation of its Medicaid program

COUNT VI
Violation of the Connecticut False Claims Act for Medical Assistance Programs
Conn. Gen. Stat. § 17b-301b

101. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

102. This is a claim for treble damages and penalties under the Connecticut Medicaid False Claims Act, Conn. Gen. Stat. § 17-b-301a, *et seq*.

103. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut State Government for payment or approval.

104. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut State Government to approve and pay such false and fraudulent claims.

105. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

106. By reason of Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

107. The State of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

108. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Connecticut in the operation of its Medicaid program.

COUNT VII
Violation of the Delaware False Claims And Reporting Act
6 Del. C. §1201(a)(1) and (2)

109. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

110. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

111. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

112. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

113. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

114. By reason of Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

115. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

116. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

COUNT VIII
Violation of the Florida False Claims Act
Fla. Stat. Ann. §68.082(2)

117. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

118. This is a claim for treble damages and penalties under the Florida False Claims Act, Fla. Stat. Ann. §68.081, *et seq*.

119. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

120. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

121. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

122. By reason of Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

123. The State of Florida is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

124. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

COUNT IX
Violation of the Georgia State False Medicaid Claims Act
Ga. Code Ann. § 49-4-168.1 *et seq.*

125. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

126. This is a claim for treble damages and penalties under the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1 *et seq.*

127. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

128. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

129. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

130. By reason of Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

131. The State of Georgia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

132. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

COUNT X
Violation of the Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)

133. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

134. This is a claim for treble damages and penalties under the Hawaii False Claims Act, Haw. Rev. Stat. §661, *et seq.*

135. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

136. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

137. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

138. By reason of Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

139. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

140. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

COUNT XI
Violation of the Illinois Whistleblower Reward And Protection Act (as amended)
740 Ill. Comp. Stat. §175/3(a)(1), (2)

141. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

142. This is a claim for treble damages and penalties under the under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq.*, as amended.

143. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

144. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

145. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

146. By reason of Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

147. The State of Illinois is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

148. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

COUNT XII
Violation of the Indiana False Claims and Whistleblower Protection Act
IC 5-11-5.5 *et seq.*

149. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

150. This is a claim for treble damages and penalties under the under the Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5 *et seq.*

151. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

152. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

153. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

154. By reason of Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

155. The State of Indiana is entitled to the maximum penalty of $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

156. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

COUNT XIII
Violation of the Iowa False Claims Act
Iowa Code § 685.2

157. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

158. This is a claim for treble damages and penalties under the under the Iowa False Claims Act, Iowa Code §§ 685.1 *et seq.*

159. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Iowa State Government for payment or approval.

160. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Iowa State Government to approve and pay such false and fraudulent claims.

161. The Iowa State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

162. By reason of Defendants' acts, the State of Iowa has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

163. The State of Iowa is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

164. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Iowa in the operation of its Medicaid program.

COUNT XIV
Violation of the Louisiana Medical Assistance Programs Integrity Law
La Rev. Stat. Ann § 46:438.3

165. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

166. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law, La Rev. Stat. Ann § 46:437.1 *et seq*.

167. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

168. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

169. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

170. By reason of Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

171. The State of Louisiana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

172. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

COUNT XV
Violation of the Maryland False Health Claims Act
MD Code Ann. § 2-602

173. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

174. This is a claim for treble damages and penalties under the Maryland False Health Claims Act, Annotated Code of Maryland § 2-601 *et seq.*

175. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Maryland State Government for payment or approval.

176. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Maryland State Government to approve and pay such false and fraudulent claims.

177. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and

continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

178. By reason of Defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

179. The State of Maryland is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

180. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Maryland in the operation of its Medicaid program.

COUNT XVI
Violation of the Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 §5B(1), (2)

181. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

182. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

183. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts Commonwealth Government for payment or approval.

184. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts Commonwealth Government to approve and pay such false and fraudulent claims.

185. The Massachusetts Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

186. By reason of Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

187. The Commonwealth of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

188. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

COUNT XVII
Violation of the Michigan Medicaid False Claim Act
MCL 400.607

189. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

190. This is a claim for treble damages and penalties under the Michigan Medicaid False Claim Act, MCL 400.601 *et seq.*

191. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

192. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

193. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

194. By reason of Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

195. The State of Michigan is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

196. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

COUNT XVIII
Violation of the Minnesota False Claim Act
Minn. Stat. § 15C.02

197. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

198. This is a claim for treble damages and penalties under the Minnesota False Claim Act, Minn. Stat. § 15C.01 *et seq.*

199. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Minnesota State Government for payment or approval.

200. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Minnesota State Government to approve and pay such false and fraudulent claims.

201. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

202. By reason of Defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

203. The State of Minnesota is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

204. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Minnesota in the operation of its Medicaid program.

COUNT XIX
Violation of the Montana False Claims Act
MCA § 17-8-403

205. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

206. This is a claim for treble damages and penalties under the Montana False Claims Act, MCA § 17-8-401 *et seq.*

207. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

208. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

209. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

210. By reason of Defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

211. The State of Montana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

212. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

COUNT XX
Violation of the Nevada False Claims Act
Nev. Rev. Stat. Ann. §§ 357.040(1)(a), (b)

213. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

214. This is a claim for treble damages and penalties under the Nevada False Claims Act.

215. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

216. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

217. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

218. By reason of Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

219. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

220. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

COUNT XXI
Violation of the New Hampshire False Claims Act
N.H. Rev. Stat. Ann. § 167:61-b *et seq.*

221. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

222. This is a claim for treble damages and penalties under the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61-b *et seq.*

223. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

224. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

225. By reason of Defendants' acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

226. The State of New Hampshire is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

227. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

COUNT XXII
Violation of the New Jersey False Claims Act
N.J.S.A. 2A:32C-3

228. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

229. This is a claim for treble damages and penalties under the New Jersey False Claims Act, N.J.S.A. 2A:32C-1 *et seq.*

230. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

231. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

232. By reason of Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

233. The State of New Jersey is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

234. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

COUNT XXIII
Violations of the New Mexico Medicaid False Claims Act, N. M. S. A. 1978, §§ 27-14-1 *et seq.* and the New Mexico Fraud Against Taxpayers Act, N. M. S. A. 1978, §§ 44-9-1 *et seq.*

235. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

236. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act, N. M. S. A. 1978, § 27-14-1 *et seq.* and the New Mexico Fraud Against Taxpayers Act, N. M. S. A. 1978, § 44-9-1 *et seq.*

237. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

238. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

239. By reason of Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

240. The State of New Mexico is entitled to the maximum penalty under of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

241. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

COUNT XXIV
Violation of the New York False Claims Act
N.Y. State Finance Law § 189

242. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

243. This is a claim for treble damages and civil penalties under the New York False Claims Act, NY State Finance Law § 187 *et seq.*

244. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

245. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

246. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

247. By reason of Defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

248. The State of New York is entitled to the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

249. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon that exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

COUNT XXV
Violation of the North Carolina False Claims Ac
N.C.G.S. § 1-607

250. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

251. This is a claim for double damages and penalties under the under the North Carolina False Claims Act, N.C.G.S. § 1-605 *et seq.*

252. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina Government for payment or approval.

253. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

254. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

255. By reason of the Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

256. The State of North Carolina is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

257. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of North Carolina in the operation of its Medicaid program.

COUNT XXVI
Violation of the Oklahoma Medicaid False Claims Act
63 Okl. St. Ann. § 5053.1

258. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

259. This is a claim for double damages and penalties under the under the Oklahoma Medicaid False Claims Act, 63 Okl. St. Ann. § 5053 *et seq.*

260. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

261. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

262. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

263. By reason of Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

264. The State of Oklahoma is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

265. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

COUNT XXVII
Violation of the Rhode Island State False Claims Act
R.I. Gen. Laws § 9-1.1-3

266. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

267. This is a claim for double damages and penalties under the under the Rhode Island State False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*

268. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

269. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

270. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

271. By reason of Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

272. The State of Rhode Island is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

273. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

COUNT XXVIII
Violation of the Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)

274. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

275. This is a claim for double damages and penalties under the under the Tennessee Medicaid False Claims Law.

276. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

277. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

278. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

279. By reason of Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

280. The State of Tennessee is entitled to the maximum penalty of $25,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

281. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

COUNT XXIX
Violation of the Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. § 36.002

282. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

283. This is a claim for double damages and penalties under the under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

284. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

285. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

286. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

287. By reason of Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

288. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

289. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

COUNT XXX
Violation of the Vermont False Claims Act
32 V.S.A. § 630 *et seq.*

290. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

291. This is a claim for double damages and penalties under the under the Vermont False Claims Act 32 V.S.A. § 630 *et seq.*

292. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Vermont State Government for payment or approval.

293. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

294. The Vermont State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

295. By reason of Defendants' acts, the State of Vermont has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

296. The State of Vermont is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

297. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Vermont in the operation of its Medicaid program.

COUNT XXXI
Violation of the Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3(A)(1), (2)

298. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

299. This is a claim for treble damages and penalties under the under the Virginia Fraud Against Taxpayers Act Va. Code Ann. § 8.01-216.1 *et seq.*

300. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia Commonwealth Government for payment or approval.

301. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia Commonwealth Government to approve and pay such false and fraudulent claims.

302. The Virginia Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

303. By reason of Defendants' acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

304. The Commonwealth of Virginia is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

305. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

COUNT XXXII
Violation of the Washington State Medicaid Fraud False Claims Act
RCW 74.66.020(1)

306. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

307. This is a claim for treble damages and penalties under the under the Washington State Medicaid Fraud False Claims Act, Revised Code of Washington 74.66.005 *et seq.*

308. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Washington State Government for payment or approval.

309. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Washington State Government to approve and pay such false and fraudulent claims.

310. The Washington State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

311. By reason of the Defendants' acts, the State of Washington has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

312. The State of Washington is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

313. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Washington in the operation of its Medicaid program.

COUNT XXXIII
Violation of the District of Columbia Procurement Reform Amendment Act
D.C. Code Ann. §1-1188.14(a)(1), (2)

314. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

315. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §2-381.01 *et seq*.

316. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

317. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

318. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

319. By reason of Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

320. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

321. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

COUNT XXXIV
Violation of the Allegheny County False Claims Act
§ 485-1 *et seq.*

322. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

323. This is a claim for treble damages and penalties under the Allegheny False Claims Act § 485-1 *et seq*.

324. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Allegheny County Government for payment or approval.

325. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Allegheny County Government to approve and pay such false and fraudulent claims.

326. The Allegheny County Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

327. By reason of Defendants' acts, the County of Allegheny has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

328. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the County of Allegheny in the operation of its Medicaid program.

COUNT XXXV
Violation of the Chicago False Claims Act
Chi. Mun. Code Ch. 1-22-020(1-2))

329. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

330. This is a claim for treble damages and penalties under the Chicago False Claims Act, Chi. Mun. Code Ch. 1-22-020(1-2).

331. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the City of Chicago Government for payment or approval.

332. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the City of Chicago Government to approve and pay such false and fraudulent claims.

333. The City of Chicago Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

334. By reason of Defendants' acts, the City of Chicago has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

335. The City of Chicago is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

336. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the City of Chicago in the operation of its Medicaid program.

COUNT XXXVI
Violation of the City of New York False Claims Act
Local Law 53, Chapter 8 § 7-801 *et seq.*

337. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

338. This is a claim for treble damages and penalties under the City of New York False Claims Act, Local Law 53, Chapter 8 § 7-801 *et seq*.

339. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the City of New York Government for payment or approval.

340. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the City of New York Government to approve and pay such false and fraudulent claims.

341. The City of New York Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

342. By reason of Defendants' acts, the City of New York has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

343. The City of New York is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

344. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the City of New York in the operation of its Medicaid program.

COUNT XXXVII
Violation of the Philadelphia False Claims Act
§ 19-3601 *et seq.*

345. Relator re-alleges and incorporates by reference the allegations in the previous paragraphs of this Complaint.

346. This is a claim for treble damages and penalties under the Philadelphia False Claims Act, § 19-3601 *et seq*.

347. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the City of Philadelphia Government for payment or approval.

348. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the City of Philadelphia Government to approve and pay such false and fraudulent claims.

349. The City of Philadelphia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal marketing practices.

350. By reason of Defendants' acts, the City of Philadelphia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

PRAYER

WHEREFORE, Plaintiff/Relator pray for judgment against Defendants as follows:

351. That Defendants cease and desist from violating 31 U.S.C. § 3729 *et seq.*

352. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States Government has and Plaintiff States have sustained because of Defendants' actions, plus a civil penalty of not less than $10,781.40 and not more than $21,562.80 for each violation of 31 U.S.C. § 3729 *et seq.* and for violations of state FCAs pursuant to the relevant statutes.

353. That Plaintiff/Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;

354. That Plaintiff/Relator be awarded all costs and expenses of this action, including attorneys' fees, pursuant to §3730(d) of the False Claims Act.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby requests a trial by jury.

Dated: January 10, 2016

Respectfully submitted:

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